

### **REMARKS / ARGUMENTS**

Claims 1-31, 38-49, and 52-78 were pending prior to this reply. In the non-final Office Action of June 10, 2009, the Examiner rejected claims 1, 6, 12-15, 19-31, 38, 41-49, 52, 56-69, and 71-78 as obvious, and objected to claims 16-18, 53 and 54. In this reply, Applicants respond to the Examiner's grounds for rejection and add new claim 79. Reconsideration of claims 1-31, 38-49, and 52-78 and consideration of claim 79 are respectfully requested.

Applicants address each of the objections and rejections in the order in which they appear in the Action.

#### **Section 103(a) Rejections Overcome**

A. Claims 1, 2-5, 7-11, 39, 40, 70, and 78 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Patent No. EP 0 469 814 A1 (Everett *et al.*) in view of U.S. Patent No. 6,698,425 (Widerström). Applicants respectfully traverse these rejections.

The Examiner argues claim 1 *et al.* are obvious over Everett in view of Widerström. Both Everett and Widerström disclose a dry powder inhaler (DPI) which uses a blister strip. In Everett, the DPI is configured to only operate on a single blister strip and to open only one blister pocket at a time. In Widerström, the DPI is configured to enable more than one blister pocket of a strip to be opened at a time and, furthermore, also indicates that the DPI can be used with more than one blister strip, each strip accessing a plurality of doses to make a complete dose when combined in a single inhalation. In this way, the DPI of Widerström is able to dispense different amounts of a medicament, by varying the number of pockets opened at one time.

With this in mind, the Examiner considers it would have been routine to modify the DPI of Everett to use plural blister strips, as disclosed in Widerström. Applicants

cannot agree with this for the following reasons: First, the isolated extraction of the use of plural blister strips from Widerström is arbitrary, ignoring both the context and detail of this disclosure. As such, it is based on hindsight of the claimed invention, not any foresight of a person of ordinary skill in the art as the date of the claimed invention.

As touched on earlier, Widerström concerns a DPI which has means to vary the number of blisters it opens in order to make a full dose when the contents of the individual doses are combined. It is clear that the blister strip(s) loaded into the DPI contains the same medicament in the pockets, since the objective of Widerström is to be able to vary the amount of a specific medicament dispensed by the DPI (col. 1, lines 8-10).

Where a single blister strip is used, Widerström describes at col. 2, lines 7-18:

*Previously, **for any one particular medicament**, it was necessary to produce a selection of blister packs having respective blisters containing different doses. For instance, one blister pack would be produced having blisters containing the powder dose for an adult and another blister pack would be produced having blisters containing the powder dose for children. Clearly, the need to produce different types of blister pack adds to their cost of production. **The present invention allows a single type of blister pack to be used for users with different needs.** For instance, for the example given above, a child could use a dose of three blisters whereas an adult could use a dose of five blisters.*

(Emphasis added)

In relation to the DPI using multiple blister strips, Widerström states at col. 6, line 66 – col. 7, line 1:

*It is also possible to construct a device which simultaneously accepts two or more blister packs **respectively containing different amounts of medicament**.*

(Emphasis added)

There is no disclosure that the respective blister packs contain different medicaments, only that the packs contain different amounts of medicament. It is clear from this, and the content of Widerström as a whole, this means each pack contains the same medicament, just different amounts in the respective blisters. Specific intrinsic evidence of this comes at col. 7, lines 7-11:

*In particular, when one blister pack strip includes smaller amounts of **the** medicament than the other strip(s) greater variability may be provided for the administered dose. One blister pack will provide coarse variability and the other blister pack fine variability.*

(Emphasis added)

It is plain from these passages that Widerström discloses having the **same medicament in each blister pack**. This is consistent with the stated object of the Widerström invention being to enable variable dosing of a single medicament (e.g. col. 1, lines 8-10).

Thus, the context of the disclosure of the multiple blister strips in Widerström is to obtain variable dosing of a particular medicament, and the detail is that each strip contains the same medicament.

Consequently, Applicants consider that the asserted combination of Everett with Widerström is unjustified since it does not reconcile the fact that the DPI of Everett is concerned only with dosing from one blister of one strip at a time (fixed dosing), and thus not suitable for combining with disclosure in a reference where the context is explicitly concerned with variable dosing of a medicament. Moreover, the asserted combination glosses over the fact that in Widerström the plural blister strips contain the same medicament, not different medicaments (*i.e.* contain the same active(s)).

So, not only is the combination of Everett and Widerström lacking foundation, being premised on inadmissible hindsight of claim 1, in any event it would not result in all features of claim 1 of the present application.

Therefore, claim 1 does involve a non-obvious, inventive and patentable step over Everett and Widerström. The claims dependent on claim 1 are equally patentable over these references, by their dependency from claim 1. The non-obvious arguments for claim 1 are equally applicable to the new independent claim.

For these reasons, the rejections under USC §103 should be withdrawn.

B. Claims 6, 12-15, 19-31, 38, 41-49, 52, 56-69, and 71-78 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Patent No. EP 0 469 814 A1 (Everett *et al.*) in view of U.S. Patent No. 6,698,425 (Widerström) and further in view of U.S. Patent No. 5,873,360 (Davies *et al.*).

Applicants respectfully traverse these additional rejections for the reasons mentioned above. Davies does not remedy the deficiencies of the proposed Everett and Widerström disclosure, as discussed above.

**CONCLUSION**

It is respectfully submitted that the present application is in condition for allowance. An early consideration and Notice of Allowance are earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR §1.16 or §1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Respectfully submitted:

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